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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/813,383

03/30/2004

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D6484

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03/13/2007

EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/813,383	DAVEY ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2006 and 19 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on September 27, 2006 and December 19, 2006, have been entered. Claims 36-40 are pending and under examination.
2. The following rejections are withdrawn:
 - The provisional rejection of claim 36 of this application in view of claims 1, 8 and 9 of Application No. 11/036,568 is withdrawn in view of the terminal disclaimer filed October 6, 2006.
 - The rejection of claims 36 and 39 under 35 U.S.C. 103(a) as being unpatentable over Dulbecco (US 4,593,002) or Young et al. (US 5,916,563), in further view of Blumenthal *et al.* (*Journal of Biological Chemistry*; 1987; 262 (28): 13614-13619), is withdrawn in view of Applicant's amendment that indicates that the enzyme of the envelope-enzyme fusion protein is encapsulated into the virus particles.
 - The rejection of claims 36, 38 and 39 under 35 U.S.C. 103(a) as being unpatentable over Russel *et al.* (WO 94/06920) and Blumenthal *et al. supra*, is withdrawn in view of Applicant's amendment that indicates that the enzyme of the envelope-enzyme fusion protein is encapsulated into the virus particles.

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- The rejection of claims 37 and 40 under 35 U.S.C. 103(a) as being unpatentable over Dulbecco or Young *et al.*, either in view of Blumenthal *et al.* as applied to claims 36 and 39 above, or Russel *et al.* and Blumenthal *et al.* as applied to claims 36, 38 and 39 above, and further in view of Goldsmith *et al.* (US 6,451,598 B1), is withdrawn in view of Applicant's amendment that indicates that the enzyme of the envelope-enzyme fusion protein is encapsulated into the virus particles.

Claim Objections

3. (*New Objection*) Claims 36-40 are objected to for the following informalities:
 - The preamble of claim 36 recites improper grammar. Suggested language is, "A method of screening for a compound that inhibits virus binding and entry to a target cell".
 - Claim 40 also recited improper grammar. Suggested language is, "carried out in a 96 well-plate".

Claims Summary and Interpretation

4. The claims are drawn to a method of screening for a compound that inhibits virus binding and entry to a target cell. This is accomplished by infecting target cells with virus particles in the presence or absence of a candidate compound. The virus particles are generated by transfection of cells with three components:
 - i) a wild type envelope protein,
 - ii) a fusion protein construct comprising virus envelope protein and an enzyme, and,

iii) plasmids encoding virus structural proteins.

Once the fusion protein construct is incorporated into virus, the fusion protein construct is further processed by a viral protease, and the enzyme portion of the fusion protein is released into the cytoplasm of the virus particle (page 4, lines 20-22). The specification teaches that this permits easy interaction with substrate (when required). After the target cells are infected with the virus particles, enzyme activity is measured in the infected cells.

In the advisory action of 10/16/06, the Examiner indicated that there was no support for the limitation, "encapsulated into the virus particles", in claim 36 and dependent claims thereof. However, upon further consideration, the specification discloses the following on page 4, lines 15 and 16:

The method requires encapsulation of a sensitive reporter enzyme, luciferase, directly into fully infectious, intact viral particles.

Therefore, the claimed limitation, "wherein the enzyme of the envelope-enzyme fusion protein is encapsulated into the virus particles", is supported by the specification as originally filed.

Claim Rejections - 35 USC § 112

5. (New Rejection) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite terms that require clarification in order to determine the metes and bounds of the claimed methods. In particular, the multiple references to viruses is confusing without further definition. For example, in claim 36, the preamble refers to a compound that

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inhibits virus binding and entry to a target cell. In the next phrase of claim 36, the claim recites, "a viral envelope protein". Is the viral envelope protein from the same virus that the compound inhibits? Further, in the next phrase of claim 36, there is mention of "wild type viral envelope protein", yet it is not clear if the wild type viral envelope protein is from the same virus that the compound inhibits, or if the wild type viral envelope protein is from the same virus as the viral envelope protein attached to the enzyme. The specification discloses pseudotyped viruses, which appears to be represented in Figure 2 of the specification. The Office requests clarification on the relationships between of the viruses mentioned in the claims.

Conclusion

6. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 3/8/07

STACY B. CHEN
PRIMARY EXAMINER